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APPLICATION NUMBER: ***60/349,367***
FILING DATE: ***January 22, 2002***
RELATED PCT APPLICATION NUMBER: *PCT/US03/02142*

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This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)

☒ *Additional inventors are being named on the* 1 *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

Device for Interpositional Arthroplasty

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 5 ☐ CD(s), Number ____

☒ Drawing(s) *Number of Sheets* 3 ☐ Other (specify) ____

☐ Application Data Sheet. See 37 CFR 1.76

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☒ Applicant claims small entity status. See 37 CFR 1.27.

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☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: ____

Respectfully submitted,

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Date 1/18/02

REGISTRATION NO. *(if appropriate)*

Docket Number:

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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Additional Page

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Docket Number	

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Number 1 of 1

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Device for Interpositional Arthroplasty

The present application describes the device and materials used for the creation of an interpositional arthroplasty using an implanted device fixed to support the structure of the original articulating surface and to generally conform to the shape of the original surface in a mammal. The device is intended for the end of a rotating, sliding or rolling bony surface such as in the knee, finger, hip, toe, spine, wrist, elbow, shoulder, ankle or TMJ joint. The device will function:

a) as an insertable, conformable spacer, that separates opposing bone to restore joint alignment
b) as an impact absorber,
c) to reduce friction during joint motion, and/or
d) to improve lubrication conditions between contacting surfaces.

To achieve these goals the device or one of its components is made from a soft, elastomeric material. The insertion of the device into the joint results ultimately in pain relief and improved function in patients with degenerative joint disease or injured or damaged joints.

The device provides good congruency by 1) use of soft elastomeric materials at bone contacting surfaces that conforms to bone surfaces and/or 2) use of material that can be further formed at time of insertion into the joint site.

The device may consist of a plurality of materials, such as polymers, including but not limited to polyurethanes, polyethyelene, polyureas, polyacrylates, rubbers, polyurethane acrylates, hydrogels of various chemical natures, epoxies, metals, biopolymers and/or hybrids of any of the above. These materials can be plasticized, reinforced, or otherwise modified in order to change or improve certain properties.

In an alternative embodiment, the device consists of a composite of materials, which may include more wear resistant surface(s), softer, more conformable surface(s) and/or inner layer(s) that provide either cushioning or support or any combinations thereof (see figure 1). In a preferred embodiment the top surface could be a highly wear resistant polyurethane and the bottom surface could be a softer, more conformable rubber material (see figure 2). These composites can be secured together by use of glue or other means of chemical adhesion, mechanical locks, insert-molded (see figure 3) or other physical means or by the use of an interpenetrating polymer network (IPN) or any combinations thereof. Alternatively, the material could be such that it exhibits a modulus gradient from the top surface to the bottom surface.

The design optionally includes materials that can be further formed at the joint site. The entire device can consist of a formable material or one or more layers of the device materials may be formable. The methods for further forming include application of heat, pressure, or irradiation (i.e. UV, visible, IR), mixing by flexing (i.e. use of frangible seals, mixing elements – see figure 4) or chemical treatment or combinations

thereof. Examples of such materials include polymers with plasticizers or fillers, heat deformable materials, materials that further react with one another upon application of heat, light, pressure and or mixing to create a more formable material. These materials can be used in combination with the local anatomy to produce the desired shape and geometry. In general, the implants are designed for optimum fit and congruency once placed in the joint site. Multiple size implants can be made off-site and the selection of the appropriate implant size could be chosen at the time of surgery.

In a preferred embodiment the materials are further formed at the joint site by heating prior to insertion and then shaping in-vivo. Alternatively, the materials can be pre-formed ex-vivo to conform to the general joint geometry or can be custom made or further machined based on Magnetic Resonance Imaging (MRI), computer tomography (CT), x-rays or other imaging of the joint site. The implants can be made directly from the images or from stereolithographic models created from the images.

Fixation methods for the device allow it to be attached to the bony surface by protrusions or lips, geometry, sutures, glues, staples, screws, or pins and any combinations thereof or by combining materials that induce ingrowth of hard or soft tissue. Optimally the fixation method does not require any violation of the surrounding bones. The fixation occurs by the use of protrusions or lips designed into the implant that conform and/or adhere to the bony surfaces. A preferred embodiment for fixation in the medial tibial plateau of the knee joint is a posterior-mesial lip (see figure 5) for long term fixation that may optionally have an anterior suture (see figure 6) to allow short-term fixation to the surrounding soft tissue.

An alternative embodiment has optimum geometries for conformance and fixation in the lateral tibial compartment of the knee joint. Such geometries may include anterior lips or ridges, opposing wedged shaped lateral dimensions in the anterior and posterior portions, saddle shaped or flat or convex or concave dimensions in the anterior-posterior dimensions (see figure 7).

The device will be especially effective when the patient will have a diagnosis of osteoarthritis and have loss of cartilage on the articulating surface. A determination will be made of the amount of correction needed for the reestablishment of a normal angle of articulation. The ligaments will be balanced so that there is no loss of range of motion with the implant in place and the device will be placed in such a position that the eventual resulting geometry reestablishes the same plane and orientation of the original articular surface, unless some correction is necessary.

Access to the site is obtained in a minimally invasive way. In the preferred embodiment, access is accomplished both by arthroscopic means and by a mini-arthrotomy with a small incision that allows the device to be inserted into the joint without sacrificing nerves, vessels, muscles or ligaments surrounding the joint. In an alternative embodiment, this is accomplished completely through arthroscopic means with arthroscopic portals. In the preferred embodiment fibrillated articulating cartilage that is degenerated is removed down to the subchondral surface. Also the medial

meniscus is resected to the outer margin. Additional site preparation including removal of bony ridges, osteophytes or other interfering tissue may be performed. Alternate embodiments could preserve all remaining cartilage.

Both the fully preformed and further formable components could be prepared from any suitable material(s). Typically, the materials include polymeric materials having an optimal combination of such properties as biocompatibility, mechanical strength and durability, and compatibility with other components and/or biomaterials used in the assembly of a final implant. Examples of suitable materials for use in preparing the fully preformed component(s) may be the same or different from the further formable component(s), and include but are not limited to polyurethanes, polyethylene, polypropylene, polyesters, polyethylene terphthalates, polyureas, hydrogels of various chemical natures, metals, ceramics, epoxies, rubber, polyisobutylene, polysiloxanes, polyacrylates, as well as biopolymers, such as collagen or collagen-based materials or the like and combinations thereof. Alternatively device could contain materials that encourage damaged tissue or cartilage growth or that are bioresorable.

Examples of suitable materials for use in preparing the further formable component, if used, include but are not limited to formable polymers such as polyurethanes, polyimides, polysulfones, polyureas, hydrogels of various chemical natures, polyurethane acrylates, copolymers, block-copolymers, IPN's, mixtures of polymers and other combinations thereof as well as naturally occurring polymers such as chitins, chitosans, elastin, collagens, carbohydrates as cellulose, and the like.

In a presently preferred embodiment, the preformed component(s) and the further formable component(s), if used, each comprises a biocompatible polyurethane. The same or different polyurethane formulations can be used to form the fully preformed component(s), as well as for the further formable component(s).

Suitable polyurethanes for use as either the fully preformed component(s) or further formable component(s) can be prepared by combining: (1) a quasi-prepolymer component comprising the reaction product of one or more hydroxyl or amino containing components such as macrodiols, products of reaction of hydroxyl containing components with difunctional or multifunctional organic acids or isocyanate or other suitable reagents, polyols, and one or more diisocyanates, and optionally, one or more hydrophobic additives or plasticizers or fillers, and (2) a curative component comprising one or more polyols, one or more chain extenders, one or more catalysts, and optionally, other ingredients such as an antioxidants, and hydrophobic additive, or hydrophilic additive.

In a preferred embodiment the fully preformed polyurethane consists of aromatic diisocyanates, polytetramethylene oxide diol(s), chain extender(s), catalyst(s) and antioxidant(s). More preferably it consists of 4,4'-diphenylmethane diisocyanate ("MDI") used either alone or in conjunction with para-phenylene diisocyanate ("PPDI").

In a preferred embodiment the polyurethane prepared from the quasi-prepolymer containing free MDI and isocyanate terminated products of reaction of PPDI and hydroxyl containing components, and does not contain any substantial amount of free PPDI monomer.

In another preferred embodiment the PPDI, or MDI and PPDI, or combination of MDI or PPDI with other di or multifunctional aromatic, aliphatic or cycloaliphatic isocyanate is used to prepare the "true-prepolymer" (i.e. a prepolymer that does not contain any unreacted or free isocyanate monomers). Then, free diisocyanate other than MDI or PPDI is added to form the quasi-prepolymer. The "true" prepolymer can be formed by the reaction of 2 or less equivalents of MDI or PPDI with 1 or more equivalents of the hydroxyl terminated components including polytetramethyleneoxide diols, polycarbonate diols for example (PC-1733, P1667, PC1122 from Stahl), and/or the diols containing both polytetramethyleneoxide and carbonate groups (PolyTHF CD from BASF), or polypropyleneoxide diols, triols or polyols, hydroxyl terminated polybutadiene, hydroxyl terminated hydrogenated polybutadiene, or other suitable hydroxyl terminated components with aliphatic saturated or unsaturated backbone, or combinations thereof.

The formable element of this invention is capable of being changed from its original shape and dimensions in order to provide the exact fit of the device to the unique joint of the particular patient. At the same time, the formable element must provide sufficient dimensional stability for years of the device service life in the physiologic environment, under the physiological loading.

The formability of the element can be achieved by using materials with specific properties such as:

Mixture with the polymer that shows a thermal transition in the temperature range between 45 and 70°C.
Interpenetrating network with the polymer that shows the thermal transition in the temperature range between 45 and 70°C.
Multiphase block copolymer where one of the phases shows thermal transition such as melting in the temperature range between 45 and 70°C.

The component or additive responsible for the formability can be of polymeric or non-polymeric nature, organic or inorganic or a mixture of several components. It also can be monolithic or porous.

The moldability can be also achieved by using the precured but not completely cured device, initially capable of developing permanent deformation under pressure in the joint. The required long-term dimensional stability then achieved as a result of post cure, which may occur in the joint at the body temperature, or using an irradiation (UV, IR) activation mechanism. The post cure of the device can also be completed outside the body by heating the device or use of an irradiation activating mechanism.

The material can be formulated as an interpenetrating network of two or more polymers where at least one of the polymers is fully cured prior to the in-vivo forming step and at least one polymer is post cured after the device is finally shaped.

As an alternative embodiment the moldable element (material) may be used to create a model of the device with perfect fit that then will be used for measurements and making the actual implant outside the body.

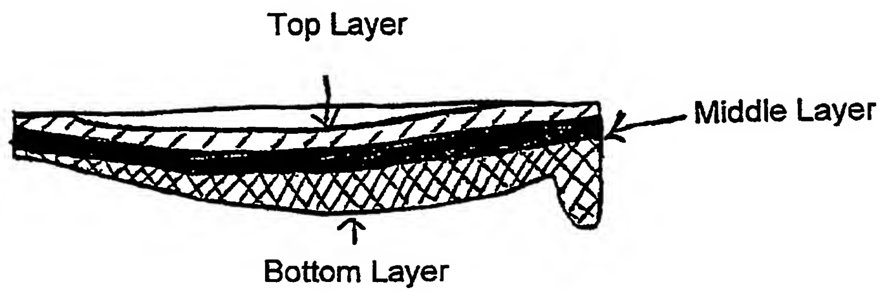

Figure 1

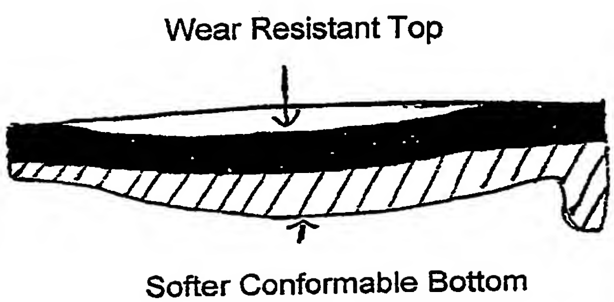

Figure 2

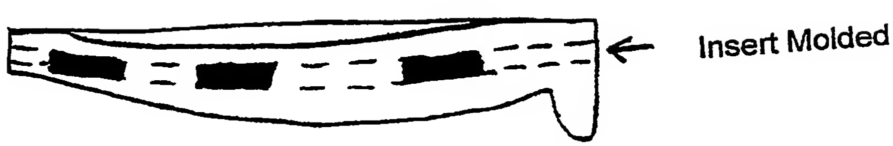

Figure 3

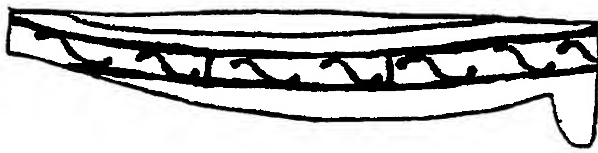

Figure 4

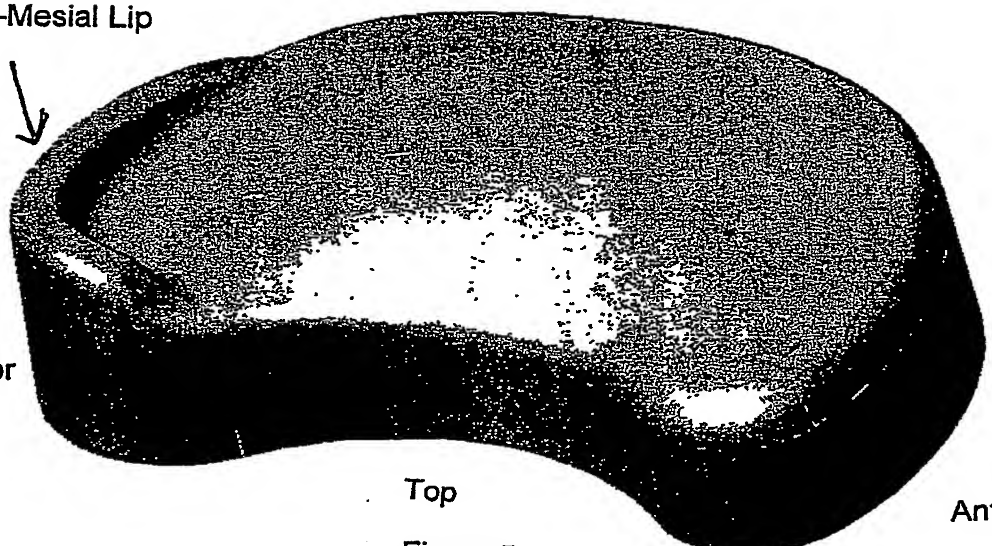

Figure 5

Medial

Disc 7/sheet 2

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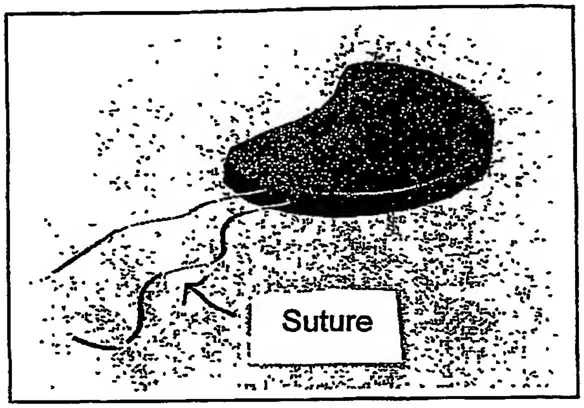
Anterior



Posterior

Figure 6

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Anterior

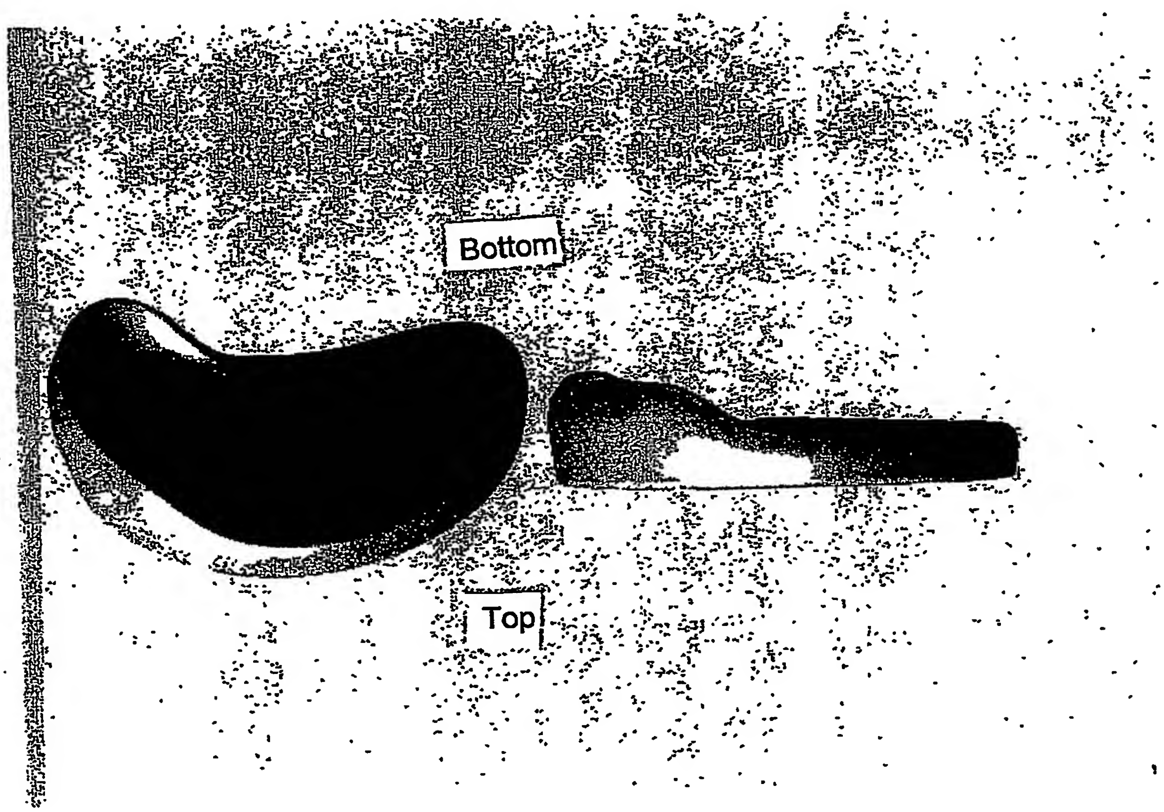

Figure 7

Lateral

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